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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,422	05/22/2000	Michel Schneider	1889-33	2399

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KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
AHMED, AAMER S	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/576,422	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,22-34 and 39-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,22-34 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *September 16 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The examiner acknowledges applicant's arguments filed September 16 2005 regarding the election of species requirement, thereby the election of species requirement is withdrawn and all amended claims will be examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9, 22-23, 32, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffiths et al U.S. Patent Number 6,317,623. Griffiths et al discloses a method of administering by injection or infusion a suspension of microparticles (col. 3 line 36) homogenously distributed in an aqueous liquid carrier by means of an injected system (320) comprising a syringe (240) containing the suspension and a power driven piston (245) for injecting the suspension into a patient comprising by subjecting the suspension in the syringe to a rotation or rocking motion, thereby maintaining the suspension homogeneous by preventing segregation of the microparticles by gravity or buoyancy without damaging the particles; and wherein the motion is provided by outside means (310) ; and wherein the motion is alternated, applied along or around the syringe longitudinal or transverse axis and the syringe is subject to continuous or intermittent rotation (col. 4 line 11). Furthermore, Griffiths et al teaches that the motion is carried out stepwise and the suspension is a contrast agent for ultrasonic imaging of

patients (see abstract), that the contrast agent comprises in suspension in an aqueous liquid carrier, gas filled microvesicles which are either microbubbles (col. 5 line 37) bounded by a gas/liquid interface made from dissolved surfactants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al in view of Trombely et al U.S. Patent Number 6,575,930. Griffiths discloses the method as described above in reference to claim 1, but fails to explicitly disclose that the motion is alternating rotation the direction of which is reversed every 360°. Trombley et al discloses a similar method including alternating rotation the direction of which is reversed every 360° (col. 6 line 6). It would have obvious to one having ordinary skill in the art at the time of invention by

applicant to modify the method of Griffiths et al by incorporating the step of alternating motion as taught by Trombley et al in order to avoid any twisting of the apparatus (col. 6 line 6).

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al in view of Schneider et al U.S. Patent Number 5,686,060. Griffiths et al discloses the method as disclosed above in reference to claim 22 but fails to disclose the type of gas or composition of the surfactant and polymers. Schneider et al discloses a similar method in which is disclosed that the gas is a halogenated gas CF_4, the gas is nitrogen (col. 6 line 60), the surfactant is a saturated phospholipids in a lamellar or laminar flow (col. 4 line 63). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Griffiths by incorporating the compositions as described by Schneider et al in order to create more stable microbubbles (col. 3 line 39).

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al and Schneider et al and further in view of Unger et al U.S. Patent Number 6,521,211. Griffiths and Schneider et al disclose the method as described above in reference to claim 24 but fail to explicitly disclose the fatty acid residue and the composition of the membrane. Unger et al discloses a similar method in which one of the phospholipids is a diacylphophatidyl (see table 1), the polymer of the membrane is selected from polyglycolic acid, the material envelope of the microballoon is made from albumin, bounded by saturated triglycerides (col. 59 line 45). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Griffiths et al and Schneider et al by incorporating the compositions as taught by Unger et al in order to increase the signal received from micobubbles and decrease background tissue signals (col. 5 line 51).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al, Schneider et al and Unger ('211) and further in view of Unger U.S. Patent Number 5,334,381. The above-mentioned references disclose the method as described above in reference to claim 32, but fail to disclose that the liposomes are filled with an iodinated compound. Unger ('381) discloses a similar method in which the liposomes are filled with an iodinated compound (col. 8 line 21). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Griffiths et al, Schneider et al and Unger ('211) by incorporating the compositions as taught by Unger ('381) in order to better detect tumors in the liver (col. 8 line 21).

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al, Schneider et al and Unger ('211) and Unger ('381) and further in view of Minchey et al U.S. Patent Number 5,415,867. The above-mentioned references disclose the method as described above in reference to claim 33, but fail to disclose that the iodine over lipid ratio is 3 or more. Minchey discloses a similar method in which the iodine over lipid ratio is 3 or more (see table 1). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Griffiths et al, Schneider et al and Unger ('211, and '381) by incorporating the compositions as taught by Minchey in order for better contrast agent detection.

Claims 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al in view of Unger ('381). Griffiths et al discloses the method as described above in reference to claims 39 and 41, but fails to explicitly disclose that the organ imaged is the liver. Unger ('381) discloses a similar method in which the organ imaged is the liver (col. 14 line 23). It would have been obvious to one having ordinary skill in the art at the time of invention by the

applicant to modify the device of Griffiths et al by incorporating the step of imaging the liver as described by Unger ('381).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 22-34, 39-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,726,650 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent discloses a device and the instant application discloses the method of using the device, furthermore, it is well settled that it is not "invention" to broadly provide a mechanical or automatic means to replace manual activity, which has accomplished the same result. In re Rundell, 18 CCPA 1290, 48 F. 2d 958, 9 USPQ 220.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4978335 A Arthur, III; William D.
US 5868710 A Battiato; Dane J. et al.
US 5611344 A Bernstein; Howard et al.
US 5317506 A Coutre; James E. et al.
US 5244461 A Derlien; Michael L.
US 5806519 A Evans, III; Russell Morrison et al.
US 5885216 A Evans, III; Russell Morrison et al.
US 4652260 A Fenton, Jr.; Paul V. et al.
US 20020072733 A1 Flaherty, J. Christopher
US 20020040208 A1 Flaherty, J. Christopher et al.
US 20030163084 A1 Griffiths, David M. et al.
US 5240322 A Haber; Terry M. et al.
US 4466442 A Hilmann; Juergen et al.
US 5896804 A Kimura; Rokusaburo et al.
US 5176646 A Kuroda; Takayuki
US 5772443 A Lampotang; Samsun et al.
US 5528923 A Ledez; Kenneth M. et al.
US 5647851 A Pokras; Norman M.
US 5997502 A Reilly; David M. et al.
US 6090064 A Reilly; David M. et al.
US 6402717 B1 Reilly; David M. et al.
US 6402718 B1 Reilly; David M. et al.
US 5401253 A Reynolds; David L.
US 5110475 A Rossling; Georg et al.
US 5176502 A Sanderson; George G. et al.
WO 9927981 A1 SCHNEIDER, MICHEL et al.
US 20020077588 A1 SCHNEIDER, MICHEL et al.
US 20030195491 A1 Schneider, Michel et al.
US 20040186425 A1 Schneider, Michel et al.
US 20040208826 A1 Schneider, Michel et al.
US 6726650 B2 Schneider; Michel et al.
US 6136293 A Schneider; Michel et al.
US 5690618 A Smith; Mark Timothy et al.
US 5910300 A Tournier; Herve et al.
US 5840026 A Uber, III; Arthur E. et al.
US 6063052 A Uber, III; Arthur E. et al.
US 6397098 B1 Uber, III; Arthur E. et al.
US 6548047 B1 Unger; Evan C.
US 6028066 A Unger; Evan C.
US 6966894 B1 Urich; Klaus
US 3812843 A Wootten; John A. et al.
US 3880138 A Wootten; John A. et al.
US 5827504 A Yan; Feng et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Ahmed

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700